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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/225,502	01/06/1999	PAUL A. MOORE	PF392	2400

22195            7590            11/12/2002  
HUMAN GENOME SCIENCES INC  
9410 KEY WEST AVENUE  
ROCKVILLE, MD 20850

EXAMINER
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DECLOUX, AMY M

ART UNIT	PAPER NUMBER
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1644  
DATE MAILED: 11/12/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application N .</b>	<b>Applicant(s)</b>
	09/225,502	MOORE ET AL.
	<b>Examiner</b>	<b>Art Unit</b>
	Amy M. DeCloud	1644

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 29 April 2002.
- 2a) This action is FINAL.                    2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 21-56 and 58-103 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 21-56 and 58-103 is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) The proposed drawing correction filed on \_\_\_\_\_ is: a) approved b) disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) The oath or declaration is objected to by the Examiner.

#### Priority under 35 U.S.C. §§ 119 and 120

- 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All b) Some \* c) None of:
1. Certified copies of the priority documents have been received.
  2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) The translation of the foreign language provisional application has been received.
- 15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                             | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____  |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)         | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____                                    |

## **DETAILED ACTION**

Applicant's Amendment filed 4-29-02, Paper No. 29, is acknowledged and has been entered.

### ***Claim Rejections - 35 USC § 112***

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

### ***Claim Rejections - 35 USC § 101***

2. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefore, subject to the conditions and requirements of this title.

MAINTAINED Claims 21-56 and 58-103 are rejected under 35 U.S.C. 101 because the claimed invention lacks a credible, substantial, specific, or well-established utility.

MAINTAINED Claims 21-56 and 58-103 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

### ***Response to Arguments***

3. Applicant's arguments filed 4-29-02 have been fully considered but they are not persuasive. Applicant traverses the rejection on the grounds that the homology of the polypeptides of SEQ ID NO:6 and 8 with FK506 Binding protein 65 (which is a potent immunosuppressant), encompasses known regions of FK506 binding as evidenced by the attached exhibits. Applicant further states that SEQ ID NO:s 6 and 8 contain four PPIase domains and that PPIase domains contain two regions within said domains that appear to be important for binding FK506. Applicants further contend that based on this homology, SEQ ID NO:s 6 and 8 are FK506-binding proteins, and that because FK506 binding proteins (FKBP) are established and useful proteins, assignment of the instant SEQ ID NO:6 and 8 imparts the same well established utility.

This is not found persuasive because Applicant has not shown that the recited proteins actually bind FK506, but only speculate the presence of this property in the polypeptides set forth as SEQ ID NO:s 6 and 8 based on sequence homology. However, even if said polypeptides

Art Unit: 1644

bind FK506, and are in fact a member of the FKBP family, the function or utility will not have been established. The Collins et al article attached to the Applicant's amendment filed 4-29-02, comments on the functional diversity of FKBP family members, and that though at the time of its publication FKBP65 was identified as a member of the FKBP based on sequence homology (the presence of three PPIase domains), the possible functions of FKBP65 were still unknown (see entire article, especially the last two paragraphs of the article). Clearly Applicant's attached reference teaches that function of a polypeptide cannot be established solely on the basis of the presence of PPIase domains.

4. WITHDRAWN Claims 38-51 and 68-80 are also rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

#### ***NEW GROUNDS OF REJECTION***

##### ***Claim Rejections - 35 USC § 112***

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 38-51 and 68-80 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

7. Claims 38-51, 68-80 and 94-103 are indefinite in their recitation of the phrase "at least 95% identical" recited in independent claims 38, 68 and 94. It is noted that the instant specification discloses the phrase "percent identity" on page 13 can be defined using one of several known computer programs. Incorporating one of these algorithms into the instant claims, would overcome this rejection.

#### ***Conclusion***

No Claim is allowed.

8. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37

Art Unit: 1644

CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amy M. DeCloux whose telephone number is 703 306-5821. The examiner can normally be reached on M-F 8:00-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on 703 308-3973. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3014 for regular communications and 703 872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703 308-0196.

Amy DeCloux, Ph.D.,  
Patent Examiner,  
November 10, 2002

*Patrick J. Nolan*  
Patrick J. Nolan, Ph.D.,  
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Group 1640